Department of Health Professions

Virginia Board of Pharmacy Law Update

VPhA Annual Convention

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Program Objectives

- Review new laws regarding:
  - §54.1-3420.1 - Proof of identity when dispensing Schedule II-V drugs;
  - §54.1-3303 - Treating other persons to prevent transmission of communicable disease.
- Review proposed regulations regarding:
  - Correction in retention of CE;
  - nominal fee for duplicate licenses and written license verifications;
  - Electronic prescriptions to conform with DEA's interim final rule on e-prescribing.

Program Objectives

- Legislative proposals regarding:
  - Multiple prescriptions per order form;
  - Scheduling tramadol and carisoprodol as CIV.
- Update on the new inspection process regarding routine inspections of pharmacies.

Proof of Identity

- §54.1-3420.1 amended by General Assembly 2010
- Board adopted guidance document 110-11 in June 2010
- Pharmacist may continue to require proof of identity prior to dispensing or refilling Schedules III-V
- Pharmacist now required to obtain proof of identity under specific circumstances when dispensing Schedule II

Proof of Identity

- If person picking up Schedule II dispensed prescription is ***the patient*** for whom the prescription is written, and the ***pharmacist knows*** that person, ***no ID or documentation*** is required.
- If person picking up Schedule II is ***the patient*** for whom the prescription is written, and ***pharmacist does not know*** that person, then he must ***require ID*** and make a ***record documenting proof of ID***.

- If ***anyone other*** than the patient for whom the prescription is written takes delivery of the drug, and ***pharmacist knows*** the person, he must ***record the person's full name and address***, but ***no ID*** is required.
- If ***anyone other*** than the patient for whom the prescription is written takes delivery of the drug, and ***pharmacist does not know*** the person, he must ***require ID***, make ***record documenting proof of ID*** and ensure that the ***person's full name and address*** have been recorded.

Proof of Identity

- "Proof of identity"
  - driver's license,
  - government-issued identification card, or
  - other photo identification along with documentation of the person's current address

Proof of Identity

- When ID required, pharmacist shall:
  - make a photocopy or electronic copy of ID, or
  - electronic record documenting that proof of identity was provided and record information only available on the ID, e.g., driver's license number.
- Maintain record for 1 year.

Proof of Identity

- Method of delivery of dispensed Schedule II drug by mail, common carrier, or delivery service to a Virginia address shall require the signature of the recipient as confirmation of receipt.

Treating other persons to prevent transmission of communicable disease

Treating other persons…communicable disease

- §54.1-3303 amended by 2010 General Assembly
- health care practitioner may prescribe Schedule VI antibiotics and antiviral agents without physical exam if person:
  - In close contact with a diagnosed patient;
  - bona fide practitioner-patient relationship with the diagnosed patient;
  - meets all other requirements for bona fide practitioner-patient relationship with the person in close contact;

Treating other persons…communicable disease

- urgency to begin treatment to prevent transmission of a communicable disease
- emergency treatment necessary to prevent imminent risk of death, life-threatening illness, or serious disability.

- Examples of applicable communicable diseases:
  - meningococcal meningitis, H. influenzae meningitis, pertussis, pandemic flu (worse than H1N1), and anthrax

Proposed Regulations

Proposed Regulation- retention of CE

- §54.1-3314.1 requires maintenance of certificates for 2 years following the renewal of license
- 18VAC110-20-90 and 18VAC110-20-106 were changed to 3 years during last regulatory review.
- Due to conflict, will amend regulations back to 2 years.

Department of Health Professions

Proposed Regulation- nominal fee for duplicate licenses and written license verifications

- Proposed fee duplicate license = $10
- Proposed fee verification of license = $25

E-Prescribing
DEA's Interim Final Rule

E-prescribing

- Regulation 18VAC110-20-285 currently allows for the electronic transmission of Schedule II-VI prescriptions.
- DEA published interim final rules which became effective June 1, 2010 and allow for electronic transmission of Schedule II-V prescriptions.

E-prescribing – Logical Access

- DEA rules are rather stringent.
- Requires application providers of electronic prescribing software or pharmacy software to use a third party auditor or approved certification body to review the application for DEA compliance and issue a report. A copy of the report will be provided to the practitioner or pharmacy.

E-prescribing – Logical Access

- A practitioner may use his electronic health record application prior to receiving an audit/certification report from the application provider, however, he must print the prescription for the patient when writing for a Schedule II-V drug and manually sign the written prescription.

E-prescribing – Logical Access

- A pharmacy may not process an electronically transmitted prescription for CII-V until its application provider has provided the pharmacy with a copy of the audit/certification report indicating compliance with DEA requirements.

E-prescribing – Identity Proofing

- Practitioner must use a two-factor credential to sign the prescription.
  - Practitioners must apply to certain Federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates.
  - Credential consists of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information).

E-prescribing

- A staff member may prepare the prescription, but the prescriber must electronically sign the prescription.
- Transmission does not have to occur simultaneously with the signing in case staff needs to add pharmacy or insurance information before transmitting.

E-prescribing

- Electronic prescription for CII-V may not be routed to the pharmacy's fax machine; CVI may continue to be routed to fax.
- If an intermediary cannot complete transmission of a CII-V electronically:
  - intermediary must notify practitioner;
  - practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy;
  - prescription must indicate that it was originally transmitted to the name of a specific pharmacy, the date and time of transmission, and the fact that the electronic transmission failed.

E-prescribing

- **Q. What should a pharmacist do if he receives a paper or oral prescription that was originally transmitted electronically to the pharmacy?**
- A. The pharmacist must check the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

E-prescribing

- **Q. What should a pharmacist do if he receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy?**
- A. The pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

E-prescribing

- **Q. What are the DEA requirements regarding the storage of electronic prescription records?**
- A. Once a prescription is created electronically, all records of the prescription must be retained electronically. As is the case with paper prescription records, electronic controlled substance prescription records must be kept for a minimum period of two years.

E-prescribing

- Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions.
- Pharmacy application service providers must back up files daily. Also, although it is not required, DEA recommends as a best practice that pharmacies store their back-up copies at another location to prevent the loss of the records in the event of natural disasters, fires, or system failures.

E-prescribing

- Board has adopted several proposed changes to regulation to conform with DEA requirements:
  - 18VAC110-20-10- definition
  - 18VAC110-20-250- Rx filing requirements
  - 18VAC110-20-285- electronic prescriptions (use of new definition, deleted other required information)
  - 18VAC110-20-290- allows electronic prescription for CII to serve as hard copy covering emergency oral prescription

Legislative Proposal

Legislative Proposal- Scheduling tramadol and carisoprodol as CIV

- June 2010-Board reviewed petition for rulemaking to schedule tramadol as a Schedule IV in regulation
- Board generally agreed tramadol and carisoprodol were known drugs of abuse and should be scheduled
- Determined would be best to follow precedence of scheduling in legislation instead of regulation

Board Inspection Process

Routine Inspection Process

- Board has revised the routine inspection form and the process used for resolving violations of law discovered during a routine inspection.
- At the conclusion, inspector will leave an inspection summary possibly a prehearing consent order imposing a monetary penalty against the pharmacy permit.
- Purpose of the new process:
  - expedite the disciplinary process associated with inspections
  - reduce costs associated with the required scheduling of informal conferences (travel costs for Board members and licensees, administrative overhead, etc.).
- Monetary penalties do NOT remain with the Board.
- All monetary penalties must be transferred by law to the Virginia Literary Fund.

Routine Inspection Process

- In September 2009, Board adopted guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm
  - Lists “major” deficiencies and “minor” deficiencies that the Board determined will result in imposing a monetary penalty.
  - Increases consistency amongst the inspectors by identifying thresholds that trigger a deficiency.
  - Eliminated some minor deficiencies that Board will not inspect for now, e.g., posting of licenses.

Routine Inspection Process

- Citing of major deficiency = monetary penalty.
- Citing of 1 or 2 minor deficiencies will NOT result in a monetary penalty.
- Citing of 3 minor deficiencies = $250 monetary penalty.
- Citing of each additional minor deficiency = additional $100 monetary penalty.

Routine Inspection Process

- Examples of major deficiencies:
  - No PIC or PIC not fully engaged in practice at pharmacy location;
  - Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists;
  - Unauthorized access to alarm or locking device for Rx department;

Routine Inspection Process

- Examples of major deficiencies:
  - Refrigerator/freezer temperature out of range +/-4 degrees;
  - No biennial inventory, or over 30 days late*;*
  - No incoming change of PIC inventory taken within 5 days;
  - Theft/loss of drugs not reported to the Board as required or report not maintained.

Routine Inspection Process

- Examples of minor deficiencies:
  - Decreased hours of operation without public/Board notice;
  - No hot/cold running water;
  - Emergency access alarm code/key not maintained in compliance;
  - Biennial taken late but within 30 days;
  - No thermometer or non-functioning thermometer, but within range, +/- 4 degrees.

Routine Inspection Process

- Examples of minor deficiencies:
  - Prescriptions not transmitted as required (written, oral, fax, electronic, etc.) - 10% threshold;
  - Records of receipt (invoices) not on site or retrievable;
  - Not properly documenting partial filling;
  - Repackaging records and labeling not kept as required or in compliance – 10% threshold.

Routine Inspection Process

Resolving Routine Inspection Deficiencies:

1. Resolve by signing and returning to the Board office the prehearing consent order, providing documentation that all deficiencies have been corrected, and submitting payment for the monetary penalty within 30 days of receiving the notice.
2. Alternatively, request an informal conference for hearing the matter, however, could result in disciplinary sanctions in addition to the monetary penalty listed on the prehearing consent order.

Routine Inspection Process

- Board Communications
  - E-newsletters published in December 2009 and July 2010.
  - Alert e-mail regarding e-newsletter publications sent to all pharmacists, pharmacy technicians, pharmacy interns, and pharmacies that have provided the Board with an email address. (Approximately 15,000 licensees).

Routine Inspection Process

- Board Communications, cont.
  - Subsequent alert email sent to those 15,000 licensees in January stating online location of the newly revised routine inspection form.
  - Pharmacists were encouraged to perform a self-inspection of their pharmacies.

Routine Inspection Process

- Thus far:
  - Piloted this process in retail pharmacies from January to June 2010.
  - Inspections went live for retail pharmacies in July.
  - Board amended inspection form and guidance document in June regarding sterile and non-sterile compounding.
  - Piloting phase began in hospitals and other compounding facilities in July.

Tips for Preparing for a Routine Inspection

- Perform a self-inspection of the pharmacy using the applicable sections of the inspection report found at http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm
- Create a folder containing:
  - Inventories (biennial and PIC changes) performed within the last 2 years;
  - Location of invoices
    - Schedule II----2 years
    - Schedule III-V----2 years
    - Schedule VI----since September 2009

Tips for Preparing for a Routine Inspection

- Location of hard copy prescriptions (2 years from date of last refill)
  - Schedule II
  - Schedule III-V
  - Schedule VI (unless maintained electronically)
- Location of dispensing data verification for previous 2 years
  - Printout
  - Separate File
  - Bound Log Book

Tips for Preparing for a Routine Inspection

- Location of records of destruction for previous 2 years;
- Location of repackaging records for previous 1 year;
- Location of applicable policies and procedure manuals.

Tips for Preparing for a Routine Inspection

- List of pharmacists and pharmacy technicians employed, both full time and part-time;
  - Original Board registrations for pharmacy technicians if primary place of work (copies for others is helpful);
  - Documentation for Board approved pharmacy technician training programs - date that technician began training, progress and completion date;
  - Documentation of site specific technician training program.

- If the pharmacist cannot produce a required document for the inspector at the time of the inspection, the pharmacy will be cited a deficiency.

Most Commonly Cited Deficiencies

- Major 8, "Refrigerator/freezer temperature out of range greater than +/- 4 degrees". $100 monetary penalty; drugs may be embargoed if found inappropriately stored.

- Minor 5, "No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees". Compliance determined by inspector's calibrated thermometer.

Most Commonly Cited Deficiencies

- Major 20, "Pharmacist not checking and documenting repackaging, compounding, or bulk packaging". Specifically, the bin filling record for the automated counting device did not include the pharmacist's initials verifying the accuracy of the process at the time the bin is refilled by a pharmacy technician.
- Major 14, "No incoming change of PIC inventory taken within 5 days".
- Minor 13, "Unable to locate invoices for Schedule VI drugs".

- Board of Pharmacy website:
  www.dhp.virginia.gov/pharmacy

- To view inspection reports, click on "Inspections" and open **76-21.1**, Pharmacy Inspection

- Email : pharmbd@dhp.virginia.gov

Questions??